US010039800B2

(12) **United States Patent**
Mosher et al.

(10) **Patent No.: US 10,039,800 B2**
(45) **Date of Patent: *Aug. 7, 2018**

(54) **LISINOPRIL FORMULATIONS**

(71) Applicant: **Silvergate Pharmaceuticals, Inc.**, Greenwood Village, CO (US)

(72) Inventors: **Gerold L. Mosher**, Kansas City, MO (US); **David W. Miles**, Kansas City, MO (US)

(73) Assignee: **SILVERGATE PHARMACEUTICALS, INC.**, Greenwood Village, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/805,934**

(22) Filed: **Nov. 7, 2017**

(65) **Prior Publication Data**

US 2018/0078604 A1 Mar. 22, 2018

Related U.S. Application Data

(63) Continuation of application No. 15/483,691, filed on Apr. 10, 2017, now Pat. No. 9,814,751, which is a continuation of application No. 15/268,095, filed on Sep. 16, 2016, now Pat. No. 9,616,096, which is a continuation of application No. 14/934,752, filed on Nov. 6, 2015, now Pat. No. 9,463,183.

(60) Provisional application No. 62/249,011, filed on Oct. 30, 2015.

(51) **Int. Cl.**

A61K 38/05	(2006.01)
A61K 9/00	(2006.01)
A61K 47/26	(2006.01)
A61K 47/12	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 38/05*** (2013.01); ***A61K 9/0053*** (2013.01); ***A61K 47/12*** (2013.01); ***A61K 47/26*** (2013.01)

(58) **Field of Classification Search**

CPC A61K 38/05; A61K 9/0053; A61K 47/26; A61K 47/12

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,374,829	A	2/1983	Harris et al.	
4,472,380	A	9/1984	Harris et al.	
4,510,083	A	4/1985	Blacklock et al.	
4,743,450	A	5/1988	Harris et al.	
4,793,998	A	12/1988	Murthy et al.	
4,830,853	A	5/1989	Murthy et al.	
4,931,430	A	6/1990	Sudilovsky et al.	
5,049,553	A	9/1991	Sudilovsky	
5,698,562	A	12/1997	Mendes et al.	
6,028,222	A	2/2000	Dietlin et al.	
6,300,361	B1	10/2001	Vivilecchia et al.	
6,300,362	B1	10/2001	Vivilecchia et al.	
6,413,988	B1	7/2002	De	
6,509,350	B2	1/2003	Vivilecchia et al.	
6,790,861	B2	9/2004	Vivilecchia et al.	
6,869,963	B2	3/2005	Patel et al.	
6,977,257	B2	12/2005	Parab et al.	
7,101,888	B2	9/2006	Reo et al.	
7,605,148	B2	10/2009	Batta et al.	
8,153,824	B2	4/2012	Sesha	
8,568,747	B1	10/2013	Rajewski et al.	
8,778,366	B2	7/2014	Rajewski et al.	
8,927,028	B2	1/2015	Grenier et al.	
9,463,183	B1 *	10/2016	Mosher	A61K 47/12
9,616,096	B1 *	4/2017	Mosher	A61K 47/12
9,814,751	B2 *	11/2017	Mosher	A61K 38/05
2004/0171669	A1	9/2004	Chenevier	
2004/0258757	A1	12/2004	Bosch et al.	
2006/0094760	A1	5/2006	Fawzy et al.	
2007/0265344	A1	11/2007	Strobel et al.	
2008/0221156	A1	9/2008	Spireas	
2008/0234291	A1	9/2008	Francois et al.	
2009/0206287	A1	8/2009	Trupke et al.	
2009/0269287	A1 *	10/2009	Berta	A61K 8/73 424/52
2010/0222334	A1 *	9/2010	Talamonti	A61K 9/0095 514/224.2
2011/0003798	A1 *	1/2011	Okram	C07D 471/04 514/224.2
2014/0100260	A1	4/2014	Rajewski et al.	
2015/0148335	A1	5/2015	Bova et al.	

(Continued)

FOREIGN PATENT DOCUMENTS

CA	1275350	C	10/1990
EP	2903690	A1	8/2015

(Continued)

OTHER PUBLICATIONS

G.L. Nicolosi, et al, the Prognositc Value of Predischarge Quantitative Two-Dimensional Echocardiographic Measurements and the Effects of Early Lisinopril treatment on Left Ventricular Structure and Function After Acute Myocardial Infarction in the GISSI-3 Trial, 17 Eur. Heart J 1646 (Year: 1996).*

Milton Packer, et al, Comparative Effects of Low and High Doses of the Angiotensin-Converting Enzyme Inhibitor, Lisinopril, on Morbidity and Mortality in Chronic Heart Failure, 100 Circulation 2312 (Year: 1999).*

Lisinopril 1mg/ml Oral Liquid (retrieved from www.uspharmacist.com) (Year: 2018).*

John Raia, et al, Angiotensin-Converting Enzyme Inhibitors: A Comparative Review, 24 DICP Ann. Pharmacother. 506 (Year: 1990).*

Mouin Seikaly, Hypertension in Children: An Update of Treatment Strategies, 19 Curr. Opin. Pediatr. 170 (Year: 2007).*

Christian Brilla, et al, Lisinopril-Mediated Regression of Myocardial Fibrosis in Patients with Hypertensive Heart Disease, 102 Circulation 1388 (Year: 2000).*

(Continued)

Primary Examiner — Sean M Basquill

(74) *Attorney, Agent, or Firm* — Wilson, Sonsini, Goodrich & Rosati

(57) **ABSTRACT**

Provided herein are stable lisinopril oral liquid formulations. Also provided herein are methods of using lisinopril oral liquid formulations for the treatment of certain diseases including hypertension, heart failure and acute myocardial infarction.

20 Claims, 2 Drawing Sheets